DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 24 2006

Re: Ovidrel
Docket No.: 2005E-0256

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 4,840,896, filed by Genzyme Corporation, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Ovidrel, the human drug product claimed by the patent.

The total length of the regulatory review period for Ovidrel is 1,787 days. Of this time, 1,485 days occurred during the testing phase and 302 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: November 1, 1995.

   The applicant claims October 2, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 1, 1995, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: November 24, 1999.

   The applicant claims November 23, 1999, as the date the new drug application (NDA) for Ovidrel (NDA 21-149) was initially submitted. However, FDA records indicate that NDA 21-149 was submitted on November 24, 1999.

3. The date the application was approved: September 20, 2000.

FDA has verified the applicant's claim that NDA 21-149 was approved on September 20, 2000.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Roger L. Browdy
Browdy and Neimark, PLLC
Suite 300
624 Ninth Street, NW
Washington, DC 20001-5303